

which might have implications in setting a trigger for MRI-informed prostate biopsy.

## SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found, in the online version, at [doi:10.1016/j.urology.2018.07.067](https://doi.org/10.1016/j.urology.2018.07.067).

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## EDITORIAL COMMENT



In this single-center study, Giannarini et al. prospectively evaluated the sensitivity values and false detection rates (FDRs) achieved by 2 experienced readers using the Prostate Imaging Reporting and Data System, version 2 (PI-RADS v2), for the detection of clinically significant cases of prostate cancer (PCa). The study included 48 patients who underwent 3 Tesla multiparametric magnetic resonance imaging (MRI) without endorectal coil before undergoing radical prostatectomy (RP). Whole-mount RP specimens were used as the reference standard, and clinically significant PCa was defined as tumors with any of the following characteristics: dimension  $\geq 1$  cm; International Society of Urological Pathology Grade Group  $\geq 2$ ; and pathologic stage  $\geq T3$ . As a secondary outcome, the authors also assessed the inter-reader agreement.

Sensitivity values were higher for patient-level analysis (73%–85%) than for lesion-level analysis (61%–75%). FDRs were significantly lower for both readers when PI-RADS v2 scores  $\geq 4$  instead of  $\geq 3$  were considered positive (0.06–0.10 vs 0.13–0.17, respectively), at the expense of a “slightly lower” sensitivity. The inter-reader agreement was substantial for PI-RADS v2 scores  $\geq 3$  and  $\geq 4$  ( $k = 0.72$  and  $0.65$ , respectively).

The results from this study add to the already large body of research and clinical experience that supports the value of MRI for the detection of clinically significant cases of PCa. Certain aspects of this study deserve to be highlighted. First, the study was performed in the context of a quality improvement program that involved routine MRI of the prostate before RP. The authors should be lauded for this initiative, as such practices are of paramount importance to validate PI-RADS v2 and to build local expertise. Second, the study used RP specimens as a reference standard, which is considered the “ground truth.” Although the inclusion of only patients who underwent RP may have introduced some bias to the study, the use of lesion-level analysis should mitigate this limitation. Lastly, in terms of trade-offs between sensitivity and FDR, the results of this study suggest that a PI-RADS v2 score  $\geq 4$  could be adopted as a threshold to trigger biopsy in order to decrease FDRs without significantly compromising sensitivity for PCa detection. In a study conducted by our group, we found a similar trend for lesions located in the transition zone but not for lesions located in the peripheral zone.<sup>1</sup> However, it is worth noting that in the study by Giannarini et al., 10.8%–21.7% of the false-negative lesions using the threshold of PI-RADS v2 score  $\geq 4$  were not intracapsular. Based on previous studies showing that the probability of PCa detection incrementally increases with increasing PI-RADS v2 scores,<sup>2</sup> it is unlikely that a single threshold will be universally adopted to dictate the need for a biopsy. Instead, PI-RADS v2 scores will need to be combined with clinical variables such as

serum prostate-specific antigen levels, PSA density, and previous biopsy histology to determine the most appropriate diagnostic pathway, as indicated in a recent publication by the PI-RADS steering committee.<sup>3</sup>

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## AUTHOR REPLY



We thank the authors for their positive notes on our study. We agree with them that prostate lesions in the peripheral zone should probably be characterized on multiparametric MRI and clinically managed subsequently in a different manner compared to those in the transition zone. It is a fact that imaging accuracy for the latter ones is still far from optimal. We move a step further by saying that prostate lesions should probably be differently characterized on multiparametric MRI depending on their location (eg, apex vs base) even when lying in the same (peripheral) zone. The possibility for a region-dependent Prostate Imaging Reporting and Data System with a different threshold for biopsy has already been alluded to by prominent experts in the field.<sup>1</sup>

We also agree with the authors of this comment that the sole characterization of prostate lesions on multiparametric MRI should not trigger a biopsy, but this should come after a thorough

multifactorial risk assessment and tailored counseling on an individual basis. This holds true especially considering the potential implications of the recent randomized PRostate Evaluation for Clinically Important Disease: Sampling Using Image-guidance Or Not? (PRECISION) trial, where upfront multiparametric MRI followed by MRI-targeted biopsy in biopsy-naïve men allowed for a significantly higher rate of detection of clinically important prostate cancer compared to standard biopsy with no MRI.<sup>2</sup> The results of this study might lead to an epochal shift in the management of men referred to early detection of prostate cancer, where MRI might be liberally ordered even by nonurologists to any-risk individual. Clearly, not all men would benefit from an upfront MRI. Truong et al. developed and prospectively validated a calculator to predict the pretest probability of detecting high-risk prostate lesions on multiparametric MRI using age, prostate-specific antigen level, and prostate volume as input variables.<sup>3</sup> Tools like this should help health care providers and patients make an informed decision on whether to undergo an upfront MRI.

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